REMARKS

Claims 63, 65-67, 70, 71 and 77-80 are pending in this application. Claims 1-62, 64, 68, 69, 72-76 and 81 were canceled. Claim 63 is amended without prejudice and without conceding to the Examiner's characterizations. Applicant believes the application to be in condition for allowance.

35 U.S.C. § 112, first paragraph

WRITTEN DESCRIPTION

The Examiner has rejected claims 63, 65-67, 70-71 and 77-80 under 35 U.S.C. § 112, first paragraph, under a written description rejection. "Applicant's claimed expression represents only an invitation to experiment regarding possible compounds suitable as sulfur derivatives, which can be used in the compositions for absorbing irritants in the skin and delivering sulfur." Applicant traverses this rejection for at least the following reasons. Applicant has amended claim 63 (and the other pending claims are dependent on claim 63) to claim only sodium sulfacetamide and sodium thiosulfate as sulfur derivatives, described in the specification. Therefore, the claims satisfy the written description requirements and Applicant respectfully requests that this rejection be withdrawn.

ENABLEMENT

Claims 63, 65-67, 70-71 and 77-80 were rejected under 35 U.S.C. § 112, first paragraph as not being enabled. The Examiner alleges that "the specification, while being enabled for using the claimed method using the compositions which has sulfur and sodium

sulfacetamide,[1] does not reasonably provide enablement for claimed method using sulfur and sulfur derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." The Examiner then sets forth eight (8) factors for evaluating whether "a disclosure would require undue experimentation." Applicant traverses this rejection for at least the following reasons. The Examiner has not met the burden of an enablement rejection under MPEP 2164.04, because it is necessary to "specifically identify what information is missing and why one of skill in the art could not supply the information without undue experimentation."

Under "state of the prior art," the Examiner asserts that sulfur at concentrations over 6% is toxic. The Examiner's contention that the use of more than 6% sulfur is toxic is simply wrong and furthermore, one of ordinary skill in the art would know and understand the invention to cover the amount of sulfur which is beneficial and non-toxic. Dr. Maibach, the author of the article cited by the Examiner, has offered a declaration attached hereto as Exhibit 1. ("Maibach Declaration") In the declaration, Dr. Maibach notes, "it was not my intent in this article to indicate that sulfur is toxic when applied topically at a concentration above 6%." (Maibach Declaration, ¶3) "It was my intent then, and my opinion now that sulfur has been safely applied topically, literally for centuries, at many concentrations, including those over 6%." (Maibach Declaration, ¶5) In fact, Dr. Maibach believes sulfur can be topically applied at concentrations of at least up to 20%. (Maibach Declaration, ¶7)

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1 Applicant has amended the claims to include sulfur and a sulfur derivative which is sodium sulfacetamide and/or sodium thiosulfate. The specification examples include sulfur, sodium sulfacetamide and sodium thiosulfate explicitly.

A noted expert in dermatology, Professor Ronald Marks, has set forth an additional declaration to this effect ("Marks' Declaration" attached hereto as Exhibit 2). Marks is a celebrated author, researcher and professor in dermatology (Marks Declaration, ¶¶ 1-5). He is also a clinical dermatologist, familiar with skin disorders and their treatments (Marks Declaration, ¶ 6). He notes that sulfur is used in topical medications, which he prescribes (Marks Declaration, ¶¶ 8 and 10). Marks reviewed the Maibach article cited by the Examiner and notes that Maibach used precipitated sulfur (6%) in petrolatum and "never [saw] an example of systemic toxicity or fatality." (Marks Declaration, ¶ 11). According to Marks, "'Dermatology,' (Braun-Falco, O., et al., p. 1156 Springer-Verlag 1991) describes pastes and ointments containing 2,10, and 20% sulphur," and another article describes the use of 10% sulfur in topical application . (Marks Declaration, ¶¶ 12-13). Several textbooks and articles recommend the topical use of sulfur as "safe and effective," including the Federal Register, which approves the use of 3-10% sulfur and none of these references mention "adverse systemic effects from its use." (Marks Declaration, ¶¶ 14-18, 21, and 23). Marks noted that the only literature he found regarding sulfur toxicity was due to ingestion of sulfur by animals in large amounts, NOT topical application. (Marks Declaration ¶¶ 19-20). According to Marks, "One of ordinary skill in the art would have no reason to believe that a 10% or less topical preparation of sulphur would cause systemic toxicity. Rather, one of ordinary skill in the art would have reason to believe that a 10% or less topical sulphur preparation is safe and effective in light of the fact that the use of 3-10% sulphur in topical over the counter drugs has been approved by the Food and Drug Administration," and has been cited approvingly in other literature. (Maibach Declaration, ¶6, Marks Declaration, ¶¶ 24 and 26) "One of ordinary skill in the art [would know and understand from the specification of this application] that sulphur and sulphur derivatives can be and are used in the treatment of dermatological conditions up to about 10%." (Marks Declaration ¶ 26).

Products having more than 6% sulfur have been used for many years, and have been specifically approved by the U.S. Food and Drug Administration ("FDA"). The FDA published acceptable concentration ranges of sulfur in topical drug products as "3 to 10 percent." See 21 C.F.R. §333.310 from 50 FR 2172, a copy of which is attached as Exhibit A to Marks Declaration.

If the Examiner is prepared to dispute the wisdom of the FDA in approving products containing as much as 10% sulfur, she should so state, and provide evidence that the FDA's actions have been in error, and refute the Maibach Declaration and Marks' Declaration. Applicant requests an affidavit by the Examiner under 37 C.F.R. § 1.104(d)(2), if the Examiner disputes Applicant's points. Absent evidence by the Examiner, one of ordinary skill in the art would know that these are acceptable ranges without undue experimentation and thus the requirements of 35 U.S.C. §112, ¶ 1 are fulfilled.

The Examiner then asserts that "the specification fails to describe the nature [of] R for the organic sulfide and the nature of R for the sulfites and inorganic sulfites. None of the sulfur derivatives are art-recognized equivalents." As noted in the argument above, "sulfur derivatives" has been amended to "sodium sulfacetamide" or "sodium thiosulfate" which are definite.

Finally, the Examiner asserts that "[d]ue to the divergent nature of the sulfur derivatives, one of ordinary skill in the art cannot extrapolate the test results to all the sulfur derivatives, and the practice of the full scope of the invention would require undue experimentation." Under MPEP § 2164.04, the examiner must "specifically identify what information is missing and why one of skill in the art could not supply the information without undue experimentation." The Examiner provides no support for the statement, "none of the sulfur compounds are art-recognized equivalents." Further, all of the pending claims have been amended to claim only sodium sulfacetamide and/or sodium thiosulfate as a sulfur derivative,

and therefore there is no experimentation required at all. The Examiner herself admitted there was sufficient support for sodium sulfacetamide. Additionally, since the Examiner has not shown that one of skill in the art would not know how to make or use the invention without undue experimentation, the Examiner did not meet the burden under MPEP 2164.04. Again, the Examiner is requested to make an affidavit under 37 C.F.R. § 1.104(d)(2) if the rejection is maintained. For all of the foregoing reasons, this rejection should be removed.

35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 63, 65-67, 70-71 and 77-80 as being indefinite because "[t]he recitation of "comprises one or more of the group consisting of" for defining the Markush group is indefinite." Applicant traverses this rejection because this phrase is not used in any of the pending claims. Applicant uses "one or more compounds selected from the group consisting of" in the pending claims, which is not indefinite.

Additionally, according to the Examiner, "[c]laims 70 and 78 are unclear as to applicant's intent. The claims recite "comprises" followed by one compound." Applicant traverses this rejection. "Comprising" or comprises is specifically addressed in MPEP 2111.03 with a clear definition set forth and therefore these claims are not unclear. Applicant requests removal of this rejection.

Obviousness-type double patenting

Claims 63, 65-67, 70-71 and 77-80 are rejected by the Examiner under obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,787,160. Applicant will provide a terminal disclaimer to overcome this rejection upon receiving allowance of the pending claims. Therefore, Applicant believes that this rejection has been overcome.

CONCLUSION

Applicant submits that the application is in condition for allowance. If the Examiner has any outstanding issues, the courtesy of a phone call is requested.

Authorization of Deposit Account

The Commissioner is hereby authorized to charge any additional fees or credit any overpayment, to Deposit Account #18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/829,426 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 703-872-9306 on the date shown below.

Maryellen Feehery

February 16, 2005
Date of Facsimile Transmission

Respectfully submitted,

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